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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/049,696	03/27/98	BILLING-MEDEL	P	6067.US.01

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EXAMINER	
KERR, J	
ART UNIT	**PAPER NUMBER**
1633	7

DATE MAILED: 10/13/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/049,696	Applicant(s) Billing-Medel et al.
	Examiner Janet M. Kerr	Group Art Unit 1633

☒ Responsive to communication(s) filed on *Jul 21, 1999* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-18* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-18* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Applicants' response to the restriction requirement, filed on 7/21/99, has been noted. Upon further consideration of the elected claims, the examiner realized that claim 12, directed to a method of making polypeptides, was inadvertantly grouped with the claims of Invention I, directed to polynucleotides. Claim 12 has now been grouped with the claims of Invention II, directed to polypeptides. This new restriction requirement supercedes the restriction requirement set forth in Paper No. 5, and allows the Applicants to reconsider the elected invention.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 11, 15, 17, and 18, drawn to a purified polynucleotide or fragment thereof, a recombinant expression system requiring the polynucleotide, a cell transfected with the recombinant expression system or the polynucleotide, a method of producing a polypeptide using the transfected cell, and a composition comprising the polynucleotide, classified in class 435, subclasses 252.8, 255.1, 320.1, 325, and 455, and class 536, subclasses 23.1 and 23.5, for example.

II. Claims 7-9, 12, and 16, drawn to a CS194 polypeptide, a method of making a polypeptide, and a composition comprising the polypeptide, classified in class 530, subclasses 300 and 350, for example.

III. Claim 10, drawn to an antibody, classified in class 530, subclass 387.1, for example.

IV. Claim 13, drawn to a method for producing antibodies which specifically bind to CS194 antigen comprising administering to an individual an isolated immunogenic polypeptide or fragment thereof, classified in class 424, subclass 185.1, for example.

V. Claim 14, drawn to a method for producing antibodies which specifically bind to CS194 antigen comprising administering to an individual a plasmid, classified in class 514, subclass 44, for example.

The inventions are distinct, each from the other because of the following reasons:

Invention I is distinct from Inventions II and III because the polynucleotides of Invention I are distinct in chemical structure and function, as well as therapeutic function, from the polypeptides of Invention II and the antibodies of Invention III. Additionally, polynucleotides, polypeptides, and antibodies can be used by materially different methods. Polynucleotides can be used as detection probes, polypeptides can be used for antigen presenting cell priming and antibodies can be used in screening assays, for example. Moreover, the polynucleotides of Invention I are not required to reduce to practice the methods of making the polypeptides of Invention II. For example, the polypeptides can be made synthetically. The differences between Invention I and Inventions II and III are further underscored by their divergent classification and independent search status.

Invention I is distinct from invention IV in that the method of claim IV is limited to *in vivo* manipulation of a polypeptide whereas the compositions and methods of Invention I can be restricted to *in vitro* use, such as using the polynucleotide as a hybridization probe, for example. Moreover, the polynucleotides of Invention I are structurally and functionally distinct from the polypeptides required in Invention IV. The differences between Invention I and Invention IV are further underscored by their divergent classification and independent search status.

Invention I is distinct from Invention V in that the polynucleotide of Invention I is not limited in use to the *in vivo* method of Invention V. It can be used by a materially different method, such as for use as a hybridization probe, for example. The differences between Invention I and Invention V are further underscored by their divergent classification and independent search status.

Invention II is distinct from Invention III because the polypeptides of Invention II are distinct in chemical structure and function, as well as therapeutic function, from the antibodies of Invention III. Additionally, polypeptides and antibodies can be used by materially different methods. Polypeptides can be used for the priming of antigen presenting cells and antibodies can

be used in screening assays, for example. The differences between Invention II and Invention III are further underscored by their divergent classification and independent search status.

Invention II is distinct from Invention IV in that the polypeptides of Invention II are not limited to *in vivo* manipulation of the polypeptides of Invention IV. Additionally, the polypeptides of Invention II can be used by a materially different method, such as priming antigen presenting cells, for example. The differences between Invention II and Inventions IV are further underscored by their divergent classification and independent search status.

Invention III is distinct from Invention IV in that the method of claim IV is limited to *in vivo* manipulation of a peptide whereas the antibodies of Invention III can be restricted to *in vitro* use, such as using the antibodies *in vitro* for screening assays, for example. Moreover, the antibodies of invention III are not required to reduce to practice the method of Invention IV, drawn to *in vivo* generation of antibodies by administering a polypeptide. The differences between Invention II and Invention IV are further underscored by their divergent classification and independent search status.

Invention III is distinct from Invention V in that the method of claim V is limited to *in vivo* manipulation of antibodies requiring administration of a plasmid, whereas the antibodies of Invention III can be restricted to *in vitro* use, such as using the antibodies *in vitro* for screening assays, for example. Moreover, the antibodies of invention III are not required to reduce to practice the method of Invention V, drawn to *in vivo* generation of antibodies by administering a polynucleotide. The differences between Invention III and Invention V are further underscored by their divergent classification and independent search status.

Invention IV is distinct from Invention V in that the *in vivo* methods of claim IV require different reagents and technical considerations from the methods of Invention V. Additionally, polynucleotides differ in their chemical nature and function from polypeptides. The differences between Invention IV and Invention V are further underscored by their divergent classification and independent search status.

The several inventions above have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet M. Kerr whose telephone number is (703) 305-4055. Should the examiner be unavailable, inquiries should be directed to Brian Stanton, Supervisory Primary Examiner of Art Unit 1633, at (703) 308-2801. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401. Any inquiry of a general nature or relating to the status of this

application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633.

Janet M. Kerr, Ph.D.
Patent Examiner
Group 1600

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER